

**REMARKS****A. Interview with the Examiner**

Applicants thank the Examiner for the courtesy extended to Applicants' representative during a telephone interview held on August 7, 2007. During the interview, Applicants discussed possible claim amendments with the Examiner, the references cited in the pending Office Action, and the prosecution history of this case.

**B. Status of the Claims and Explanation of the Amendments**

In Applicants' previous amendment, filed April 4, 2007, Applicants had cancelled original claims 1-39 and added new claims 40-137. However, the Examiner withdrew claims 41-84, and 86-137 as directed to non-elected subject matter. Thus, the claims currently under examination are claims 40 and 85. However, for the reasons set forth herein, Applicants respectfully submit that withdrawn claims 41-84 and 86-89 should be examined, because they are within the elected subject matter. Accordingly, Applicants respectfully traverse the withdrawal of claims 40-84 and 86-89.

In this paper, Applicants have requested the cancellation of claims 90-137. This cancellation is made without prejudice or disclaimer, and Applicants reserve the right to file and to prosecute claims directed to the cancelled subject matter in future continuation applications.

Applicants also have amended claims 40 and 85 to make them more consistent with species (ii/v), which had been elected previously by Applicants in response to an election/restriction requirement dated June 21, 2004. In amending claims 40 and 85, some claim elements were deleted. These deletions are made without any prejudice or disclaimer, however,

and Applicants hereby reserve the right to file and to prosecute claims directed to the deleted subject matter in future continuation applications.

Additionally, amended claims 40 and 85 recite, *inter alia*, “wherein each of said biological agents is...not a nucleic acid.<sup>1</sup>” Support for these amendments is generally throughout the specification. For example, the specification gives numerous examples of biological agents that are not nucleic acids (e.g., see p. 15, line 20 to p. 17, line 10). Accordingly, Applicants respectfully submit that no new matter has been added by these amendments.

Claims 40 and 85 stand rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Wu et al. (hereafter “Wu”) as published in J. Biol. Chem. 262(10):4429-4432, 1987), as evidenced by GenBank Accession No. M77788 (2005).

Claims 40 and 85 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent Application No. 20030236214 to Wolff et al. (“Wolff”). Additionally, claims 40 and 85 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Wolff in view of PCT Application No. WO 99/24596 to Ledebur et al (“Ledebur”).

C. The Objection to Claims 40-84 and 86-89 Should Be Withdrawn Because They Correspond to An Elected Species

The Examiner objects to claims 41-84 and 86-89, contending that these claims are “drawn to non-elected subject matter” [May 14, 2007 Office Action, p. 3, lines 6-7]. Applicants respectfully disagree with this objection and request reconsideration of these claims in view of the following remarks.

On June 21, 2004, Applicants submitted a response to the Examiner’s election/restriction requirement, in which Applicants provisionally elected to prosecute Group I,

species (ii/v). In accordance with the enumerated Markush group species set forth in original claim 1, species (ii/v) is defined as those embodiments of Applicants' invention involving "a positively charged backbone," plus Markush group species (ii) (i.e., "a negatively charged backbone having a plurality of attached targeting agents") and Markush group species (v) (i.e., "a negatively charged backbone having a plurality of attached biological agents").

In Applicants' response dated April 4, 2007, Applicants added new independent claims 40 and 85, which are substantially the same as original claim 1, except that they additionally recite that the biological agent is either a "therapeutic agent" (claim 40) or a "cosmeceutical agent" (claim 85).

Moreover, Applicants added dependent claims 41-84 and 86-89, which depend from independent claims 40 and 85. Claims 41-84 are directed to some of the specific biological agents embodied by species (ii/v), as exemplified in the specification (e.g., see specification, pp. 15-17). Claims 86-89, which depend directly or indirectly from amended claim 40, are also directed to species (ii/v). In fact, claim 89 recites a composition comprising non-covalent complex comprising a positively charged backbone having a formula (gly)<sub>p</sub>-RGRDDRRQRRR-(gly)<sub>q</sub> (SEQ ID NO: 19), a negatively charged backbone comprising a plurality of targeting moieties, and a negatively charged backbone having attached botulinum toxin molecules. This specific composition has already been examined by the Examiner and deemed "free of the art":

However, as previously indicated in the action of 10/4/06, the species of a non-covalent association complex of a positively charged backbone polymer having positively charged branching groups of the formula (gly)<sub>p</sub>-RGRDDRRQRRR-(gly)<sub>q</sub> (SEQ ID NO:19), a negatively charged backbone comprising a plurality of attached targeting moieties, and a negatively-charged backbone having a plurality of attached BOTOX molecules is free of the art [May 14, 2007 Office Action, page 2].

Accordingly, Applicants respectfully maintain that claims 41-84 and 86-89 fall within elected species (ii/v) and should be within the elected species under examination. Applicants respectfully request reconsideration and withdrawal of the objection to these claims.

D. Applicants' Amended Claims Are Not Anticipated by Wu

Applicants respectfully traverse the rejection of claims 40 and 85 under 35 U.S.C. § 102(b) for allegedly being anticipated by Wu. Briefly, Wu does not disclose all of the claim elements in Applicants' claims as amended. Accordingly, the rejection should be withdrawn. MPEP § 2131.

Wu is directed to a soluble DNA carrier system that complexes poly-L-lysine with DNA. To test this delivery system, Wu employed its DNA carrier system to deliver plasmid pSV2 CAT (a bacterial plasmid) to mammalian cells [Wu, p. 4429, col. 2, first full paragraph].

In the May 14, 2007 Office Action, the Examiner takes the position that Wu anticipates Applicant's claims, because Wu allegedly teaches Applicants' species (iii/iv) by describing a selectable marker in plasmid pSV2 CAT (which the Examiner reads as "a persistence factor") and "DNA" [see, May 14, 2007 Office Action at page 4]. Applicants' amendment to claims 40 and 84, which deletes element (iv) relating to DNA encoding at least one persistence factor renders this ground of rejection moot.

However, whether Wu teaches Applicants' species (iii/iv) is moot in view of the foregoing amendments to the claims. In particular, Applicants respectfully note that amended claims 40 and 85 no longer recite Markush group species (iii) or (iv).

Moreover, amended claims 40 and 85 state that "each of said biological agents" is either "a therapeutic agent" (claim 40) or a "cosmeceutical agent" (claim 85), and in both cases

is “not a nucleic acid.” Since there is nothing in Wu relating to using its delivery system to delivery any other type of molecule besides a nucleic acid, Applicants’ amendment to claims 40 and 85 stating that the therapeutic agent or cosmeceutical agent is not a nucleic acid also renders this ground of rejection moot.

Thus, Applicants respectfully submit that Wu fails to disclose all claim elements of Applicants’ claims 40 and 85. Accordingly, Applicants respectfully request the that the rejection of these claims under 35 U.S.C. § 102(b) as being anticipated by Wu be withdrawn. See MPEP § 2131.

Claims 41-84 and 86-89, which depend from claims 40 and 85, respectively, and which Applicants maintain should be under examination, are also not anticipated by Wu for reasons similar to the foregoing. Applicants respectfully request reconsideration and allowance of these claims.

#### E. Claims 40 and 85 Are Patentable Over Wolff

Applicants respectfully traverse the rejection of claims 40 and 85 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Wolff. Wolff fails to teach or suggest all of the claim elements of Applicants’ amended claims. Accordingly, the rejection should be withdrawn. MPEP § 2143.

The Examiner contends that “Wolff [teaches] a positively charged complex comprising (1) polycation, (2) DNA, RNA, ribozyme, or modified oligonucleotide, and (3) a third polyanion comprising a targeting moiety” [May 14, 2007 Office Action, p. 6]. Moreover, while the Examiner acknowledges that Wolff does not teach a plurality of targeting agents, the Examiner states that “the number of targeting agents attached to the polyanion is considered to

be a matter of design choice and is therefore obvious” [May 14, 2007 Office Action, p. 5, fifth paragraph]. On this basis, the Examiner concludes that “...Wolff renders obvious an embodiment of the invention comprising items (ii) and (iii) of [claim] 40...” [May 14, 2007 Office Action, page 7].

As noted above, however, Applicants have deleted Markush group species (iii) and (iv). Thus, the Examiner’s rejection as set forth in the foregoing paragraph is moot.

Moreover, Applicants’ amended claims 40 and 85 state that the “each of the biological agents” is either a “therapeutic agent” (claim 40) or a “cosmeceutical agent” (claim 85), and in both cases “is not a nucleic acid” (emphasis added). Nowhere does Wolff teach or suggest the non-nucleic acid biological agents recited in amended claims 40 and 85. Because Wolff fails to teach or suggest all of the claim elements of claims 40 and 85, the rejection of these claims under 35 U.S.C. § 103(a) for being unpatentable over Wolff should be withdrawn. MPEP § 2143. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

#### F. Applicants’ Claims Are Patentable Over Wolff in view of Ledebur

The Examiner contends that Ledebur describes a plasmid vector for genetic immunization comprising two therapeutic genes (i.e., a first antigen encoding gene and a second gene encoding an antigen or costimulatory protein) [May 14, 2007 Office Action, page 7]. On this basis, the Examiner concludes that “[t]his represents a negative charged backbone (the plasmid strand comprising the two genes) and two attached therapeutic agents, i.e. the two therapeutic genes” [May 14, 2007 Office Action, page 7].

However, amended claims 40 and 85 now recite a “negatively charged backbone having...attached biological agents... wherein each of said biological agents is...not a nucleic acid” (emphasis added). Neither Lebedur nor Wolff teach or suggest the “biological agents” recited in amended claims 40 and 85.

Accordingly, because Wolff and Lebedur, whether taken alone or together, fail to teach or suggest all of the claim elements of independent claims 40 and 85, the rejection of these claims under 35 U.S.C. § 103(a) over these references should be withdrawn. MPEP § 2143. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

**CONCLUSION**

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and allowance of this application.

**AUTHORIZATION**

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-3732**, Order No. 13720-105065US1. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 13720-105065US1.

Respectfully submitted,  
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